APR - 5 2002

SUMMARY OF SAFETY AND EFFECTIVENESS:

This safety and effectiveness summary for the Ortho Development Envision Anterior Cervical Plate System is provided as required per Section 513(i)(3) of the Food, Drug, and Cosmetic Act.

1. Submitter:
   Ortho Development Corporation
   12187 South Business Park Drive
   Draper, Utah 84020

2. Contact Person:
   Carol Freasier
   Telephone: (801) 553-9991
   Fax: (801) 553-9993

3. Date Prepared:
   February 27, 2002

4. Name of the Device

Trade Name:	Ortho Development Envision Anterior Cervical Plate System
Proprietary Name:	Envision Anterior Cervical Plate System
Common Name:	Appliance, Fixation, Spinal Intervertebral Body Orthosis
Classification Name:	Spinal Fixation System
Product Code:	KWQ
Reference:	(888.3060)

5. Description of the Device:
   The Ortho Development Envision Anterior Cervical Plate System system is a cervical spinal fixation device, which consists of a variety of bone plates and bone screws. Fixation is provided by the insertion of bone screws thought the openings at each end of the plate into the anterior portion of vertebral bodies of the cervical spine.

   Materials: The devices are manufactured from Ti-6Al-4V alloy per ASTM F-136.

   Function: The Envision Anterior Cervical Plate System functions to provide a means to fuse the cervical spine.

6. Intended Use:
   The Envision Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine at levels C_2-T_1. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with :
   - Degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
   - Spondylolisthesis
   - Trauma (i.e., fracture)
   - Tumer
   - Deformity (i.e., kyphosis, lordosis, and scoliosis)
   - Spinal stenosis
   - Pseudarthrosis

- Failed previous fusion

7. Predicate or legally marketed devices which are substantially equivalent:
   - Synthes Anterior CSLP System (Synthes)
   - EBI Vuelock Anterior Cervical Plate System (EBI)
   - Window Cervical Dynamic Plate System (Advanced Spine Technology)

8. Comparison of the technological characteristics of the device to predicate and legally marketed devices:
   There are no significant differences between the components of the Ortho Development Envision Anterior Cervical Plate System and other commercially available cervical plating systems currently being marketed, which would adversely affect the use of the product.

   Mechanical testing shows the biomechanical performance of the subject device to be similar to the performance of previously cleared spinal systems with similar indications. It is substantially equivalent to these other devices in design, function, material and intended use.

9. Non-clinical Performance and Conclusions:

   The Food and Drug Administration have established no performance standards applicable to anterior cervical plating systems. However, static and fatigue compression and static torsion testing of the Envision Anterior Cervical Plate System were performed according to ASTM F1717-96. Data regarding the functional performance of the proposed Envision Anterior Cervical Plate System has been generated.

10. Clinical Performance and Conclusion:

    Clinical data and conclusion were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Carol Freasier
Regulatory Affairs
Ortho Development Corporation
12187 S. Business Park Drive
Draper, Utah 84020

APR - 5 2002

Re: K020649
Envision Anterior Cervical Plate System
Regulation Number: 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: II
Product Code: KWQ
Dated: February 27, 2002
Received: February 28, 2002

Dear Ms. Freasier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K020649

Device Name: Envision Anterior Cervical Plate System

Indications for Use

The Envision™ Anterior Cervical Plate System is intended for the treatment of the cervical spine in skeletally mature patients receiving fusion by autogenous and/or allogenic bone graft. The implants are attached to the anterior cervical spine (C2-T1) with removal of the implants after the attainment of a solid fusion mass. The Envision™ Anterior Cervical Plate System is intended for use under the following indications:

- Degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Trauma (i.e., fracture)
- Tumor
- Deformity (i.e., kyphosis, lordosis, and scoliosis)
- Spinal stenosis
- Pseudarthrosis
- Failed previous fusion

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020649

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)